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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,964	07/06/2000	KEITH B HOFFMAN	THUR-001	4643

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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	PAPER NUMBER
1617	18

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Prevent

~~435~~ 431, 461, 47, 51

54T-58

Thrombin cyclo carboxy
side of deptide at Arginine
when as Trypsin cleaves the Arginine
& Lysine. Thus Thrombin inhibitor
Tough by Friedrich is
a species in the genus claimed
herein. (See page 2)

S.M

Office Action Summary

Application No.	Applicant(s)
09/582,964	Hoffman et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 23, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *43-54* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *43-54* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment and request for continuing prosecution filed January 23, 2003 have been received and entered into the file.

Applicant's arguments filed January 23, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 43-54 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define neither, those pathologies with etiologies resulting from "an undesirable increase in synaptic responsiveness", nor a pathology "resulting from excessive activity of glutamate receptors", nor those compounds useful in providing therapeutic relief for such pathological conditions. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of pathologies with etiologies resulting from "an undesirable increase in synaptic responsiveness", nor a pathology "resulting from excessive activity of glutamate receptors", or those compounds useful in providing therapeutic relief for such pathological conditions examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all pathologies with etiologies resulting "an undesirable increase in

synaptic responsiveness", or a pathology "resulting from excessive activity of glutamate receptors", and those compounds useful in providing therapeutic relief for such pathological conditions, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 43-44, 46-52 and 54 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Additionally, Applicants fail to set forth the criteria that define those situations wherein those pathologies with etiologies resulting from "an undesirable increase in synaptic responsiveness", nor a pathology "resulting from excessive activity of glutamate receptors" could be prevented. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these situations without undue experimentation. In the instant case, only a limited number of pathologies with etiologies resulting from "an undesirable increase in synaptic responsiveness", or a pathology "resulting from excessive activity of glutamate receptors", and no examples are set forth illustrating a situation where these conditions are prevented, thereby failing to provide sufficient working examples. It is noted that these examples are not exhaustive. The pharmaceutical art is unpredictable, requiring each embodiment to be

individually assessed for physiological activity. The instant claims read on preventing all pathologies with etiologies resulting "an undesirable increase in synaptic responsiveness", nor a pathology "resulting from excessive activity of glutamate receptors", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 51-54 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 43-44, 46-52 and 54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43-44, 46-52 and 54 are rendered indefinite by the phrases "an undesirable increase in synaptic responsiveness", or "resulting from excessive activity of glutamate receptors", and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments therapeutically useful for treating those pathologies flowing from "an undesirable increase in synaptic responsiveness", nor a pathology "resulting from excessive activity of glutamate receptors" are not clearly defined in the instant application, thus, rendering the instant claims properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 43-54 are rejected under 35 U.S.C. § 103 as being unpatentable over Friedrich, Okajima et al, Veronesi et al and Pinsky et al, in view of Kazmirowski et al.

Friedrich, Okajima et al and Veronesi et al teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicament are taught as useful for treating neurological pathologies, to include seizures, motor functional disturbances, ischemia and trauma. Claims 43-54, and the primary references, differ as to:

1) the recitation of Applicants hypothesized mechanism by which the therapeutic method is effected, and

2) teaching anti-protease compounds as providing therapy for neuropathic conditions; or the claimed compounds as possessing various anti-protease activity.

The instant claims are directed to treating various neuro-pathologies, vis-a-vis effecting various neural biochemical pathways with old and well known compounds. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not posses the characteristic, on which Applicant has relied. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter

obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Pinsky et al teach compounds possessing anti-proteolytic activity as providing prophylaxis and therapy for various neuro-pathologies herein recited. Kazmirowski et al teach the claimed compounds as possessing irreversible protease inhibition for those proteolytic enzymes herein claimed. Possessing the Pinsky et al teaching of employing peptidase inhibitors to therapeutic uses, to include epileptiform seizure activity, the skilled artisan would have seen as obvious, employment of the Kazmirowski et al enzyme inhibitors for those therapies taught by Pinsky et al.

RESPONSE TO ARGUMENTS

Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage

does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Rebuttal arguments regarding the obviousness rejection are unconvincing. As stated above, the claims simply outline some biochemical pathway believed to have a nexus for various disease conditions. Examiner cited prior art teaches those compounds herein recited as protease inhibitors as old and well known for the use herein claimed, albeit absent the proposed biochemical pathways. All prior art cited by Examiner teaches the claimed compounds as providing anti-seizure activity, to include epileptiform seizure activity (see Pinsky et al). Simply stated, the discovery of those pathways believed to mediate the pathology fail to impart patentable subject material to otherwise obvious subject matter.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers
Primary Examiner
Art Unit 1617